Att'y Dkt. No.: 358275.20020

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

MUKAIDA, et al Art Unit:

Appl. Serial No.: 10/567,681 Examiner:

Filing Date: February 9, 2006 Atty. Docket: 358275.20020

Title: Polypeptide Specific to Liver Cancer, Polynucleotide Coding for the Polypeptide, and

RNA Molecule Inhibiting Expression of the Polypeptide

## INFORMATION DISCLOSURE STATEMENT

U.S. Patent and Trademark Office Customer Window, Mail Stop Amendment Randolph Building Alexandria, VA 22314

Sir:

Listed on the accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that an exhaustive search has been made, or that there does not exist information more material to the examination of the present patent application. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will review art of record in all 35 U.S.C. § 120 priority documents.

☑1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No certification or fee is required.

Att'y Dkt. No.: 358275.20020

2. The Information Disclosure Statement is being filed more than three months after the U.S. filing late AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.						
	□a. I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).					
	□b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56 (c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).					
	☐c. Attached is our check no in the amount of \$ in payment of the fee under 37 C.F.R. § 1.17(p).					
Issue F	3. This Information Disclosure Statement is being filed more than three months after the U.S. filing ate and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the saue Fee. Applicants hereby petition that the Information Disclosure Statement be considered. Attached sour check no in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p).					
	□a. I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).					
	□b. I hereby certify that no item of information on this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).					
□4.	Relevance of the non-English language documents is discussed in the present specification.					
	The document(s) was/were cited in a corresponding foreign application.   A copy of a search issued in the foreign application is attached.   An English language version of the foreign search is attached for the Examiner's information. M.P.E.P. § 609 (A)(3).					
□6. hereto	A concise explanation of the relevance of the non-English language document(s) is attached or appears below.					

Att'y Dkt. No.: 358275.20020

<b>□</b> 7.	The Examiner's attention is directed to co-pending U.S. Patent Application No, filed, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.				
□8.	Copies of the documents were cited by or submitted to the Office in Application No, filed, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).				
⊠ 9.	Other: Documents were cited in the International Search Report.				
	It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449,				
and to	indicate in the official file wrapper of this patent application that the documents have been				
conside	ered.				
	The Commissioner is hereby authorized to charge any fee deficiency, or credit any overpayment,				
to our I	Deposit Account No. 50-0622				
	Respectfully submitted,				
	REED SMITH LLP  By: Mark Sharks				
	Mark R. Shanks Reg. No. 33,781				
Date: _	10/27/06				
Suite 1	hurch, VA 22042 PATENT TRADEMARK OFFICE				

Form PTO 1449	ATTY, DOCKET NUMBER	SERIAL NUMBER	·	
	358275.20020	10/567,681		
U.S. Department of Commerce	MUKAIDA, et. al.			
Patent and Trademark Office	FILING DATE	GROUP		
	February 9, 2006			
Information Disclosure Statement by Applicant				

U.S.	Patent	Documents
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Examiner Initial	DOCUMENT NUMBER	DATE	Name	CLASS	SUB- CLASS	FILING DATE
	6,383,791 B1	May 7, 2002	Kapeller	<u> </u>		Aug. 23, 2000
	6,143,540	Nov. 7, 2000	Kapeller			Jan. 26, 1999
	2002/0115120 A1	Aug. 22, 2002	Kappeller-Libermann, et al.			Oct. 4, 2001
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## Foreign Patent Documents

Examiner	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-	Trans	LATION
Initial					CLASS	YES	No
	WO 03/060130 A2	Jul. 24, 2003	PCT			X	•
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N. L.	1001	1.0		1		l	

Other Documents (Including Author, Title, Date Pertinent Pages, Etc.)

	<ul> <li>Nakamoto, Y., Guidotti, L.G., Kuhlen, C.V., Fowler, P. and Chisari, F.V. 1998. Immune pathogenesis of hepatocellular carcinoma, J. Exp. Med., 188(2):341-350.</li> <li>Chisari, F.V., Fillipi, P., McLachlan, A., Milich, D.R., Riggs, M. Lee, S., Palmiter, R.D., Pinkert, C.A., and Brinster, R.L. 1986. Expression of hepatitis B virus large envelope polypeptide inhibits hepatitis B surface antigen secretion in transgenic mice. J. Virol. 60:880-887.</li> </ul>				
	Wirth, S., Guidotti, L.G., Ando, K., Schlicht, H.J., and Chisari, F.V. 1995. Breaking tolerance leads to autoantibody production but not autoimmune liver disease in hepatitis B virus envelope transgenic mice.  J. Immunol. 154:2504-2515.				
	Moriyama, T., Guilhot, S., Klopchin, K., Moss, B., Pinkert C.A., Palmiter, R.D., Brinster, R.L., Kanagawa, O., and Chisari, F.V. 1990.; Immunobiology and pathogenesis of hepatocellular injury in hepatitis B virus transgenic mice. Science 248:361-364.				
	Ito, T., and Sakaki, Y. 1999. Fluorescent differential display: a fast and reliable method for message display polymerase chain reaction. Methods enzymol. 303:298-309.				
	Kitamura, K., Nakamoto, Y., Akiyama M., Fujii, C., Kondo, T., Kobayashi, K., Kaneko, S., and Mukaida, N. 2002. Pathogenic roles of tumor necrosis factor receptor p55-mediated signals in dimethylnitrosamin-induced murine liver fibrosis. Lab. Invest. 82:571-583.				
	Elbashir, S.M., Harborth, J., Weber, K., and Tuschl, T. 2002. Analysis of gene function in somatic mammalian cells using small interfering RNAs. Methods. 26(2):199-213.				
Examiner		DATE CONSIDERED			

EXAMINER: Initial if citation is considered, whether or not citation is in conformance with MPEP 609; draw a line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant